K010724

Dräger

JUN - 7 2001

510(k) Summary (Section 2.1)

Summary of Safety and Effectiveness

Applicants Name and Address

Dräger Medizintechnik GmbH
Moislinger Allee 53-55
D-23542 Lübeck
Germany

Applicants Contact Person

Mr. Ulrich Schröder
Manager Regulatory Affairs

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Applicants US Contact Person

Mr James J. Brennan
Director Regulatory Affairs

Tel. No.: (215) 721-5400
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Date the Summary was prepared

March 9, 2001

Device Name

Trade Name:	**SOLA 700 / 500 / 300**
Common Name:	Surgical and Examination Light (SOLA 700, 500) Examination Light (SOLA 300)
Product Classification:	Class II
Product Code:	80 FTD
Classification Name:	Lamp, Surgical (per 21 CFR 878.4580)

Legally marketed device to which Substantial Equivalence is claimed:

Brightstar (K981081)
by Hill-Rom, Inc., USA

Hanaulux Blue 80 and 30 (K954169)
by Heraeus Med GmbH, Germany

SOLA 700, 500 and 300 (K984611)
by Dräger Medizintechnik GmbH, Germany

Description of the Device

The SOLA series of surgical and examination lights was developed and is manufactured at the Dräger headquarter in Germany, the Dräger Medizintechnik GmbH, Lübeck, Germany. The predecessor of the completely redesigned series of lightning systems have been marketed and distributed under the same name, but have been designed and manufactured by a subcontractor. The SOLA predecessor received premarket notification approval in March 1999 (K984611). The currently marketed SOLA lamps as well as competitor devices serve as predicate devices to which substantial equivalence is claimed. The currently marketed SOLA series of operating lights will be discontinued when distribution of the new series starts.

The re-engineered SOLA family is intended to locally illuminate various operating areas of the patient's body and during medical examination treatments with high intensity light. In order to provide a full portfolio of lightning systems in the operating theatre, Dräger developed the Sola surgical lights with a variable illumination level of 145 klx by Sola 700, 90 klx by Sola 500 and 40 klx by Sola 300 in all desired combinations up to three light heads. Combination with Dräger ceiling supply units is optional.

Sola lights are based on single bulb technology. The parabolic shape of the reflector generates a high degree of depth illumination. An excellent shadow resolution was accomplished due to the facet interface of the reflector. A filter unit surrounds the light source, correcting the color temperature and filtering out infrared and ultra-violet radiation.

SOLA 700 and 500:

The lamps consist of the light head, adapted to a double articulated arm system with horizontal rotation and height adjustment. The arm system is fixed to a ceiling suspension tube. Additionally, the Sola 500 is available as a wall mounted version. Guiding the light head is easily done either by the central sterilizable handle or special designed surrounding grasps served by the non- sterile nurses. SOLA 700 and 500 feature a replacement bulb, which is immediately moved into the focal point of the reflector by means of swivel plate in case of a main bulb failure.

SOLA 300:

Sola 300 is also suitable for medical diagnostics in examination rooms, by the preparation in induction and awake areas as well as for support minimal surgical operations on the patient's bed in the intensive care. Sola 300 is available as a wall and ceiling-mounted light. It consists also of the light head, the double articulated arm system and the appropriate adaption to wall or ceiling.

Intended Use

Dräger SOLA 700 and SOLA 500 surgical and examination lights are intended for local illumination of the operating and examination area of the patient in theatres and treatment rooms.

Dräger SOLA 300 examination lights are intended for local illumination of the examination area of the patient in treatment rooms.

Substantial Equivalence

The intended use of the new SOLA series is covered by the referenced predicate devices. The materials and design are also similar to those predicate devices. The technical characteristics of the new SOLA 700, 500 and 300 do not raise new questions regarding safety or effectiveness of surgical and examination lights. Furthermore, the labeling of the new SOLA provides similar information compared to the predicate devices.

Information provided in the 510(k) submission supports the determination of substantial equivalence. The structure of the 510(k) submission complies with the Guidance Document for Surgical Lamp 510(k)s, issued by FDA's General Surgical Devices Branch on July, 1998. All aspects have been addressed accordingly. Performance testing was conducted using the IEC 60601 series of standards and other international and company internal standards. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

In summary Dräger Medizintechnik GmbH has demonstrated the new SOLA series of surgical and examination lights to be safe and effective. The new SOLA 700, 500 and 300 are considered to be substantial equivalent to currently marketed devices which have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2001

Dräger Medizintechnik GmbH
c/o Mr. James J. Brennan
Director, Regulatory Affairs
Draeger Medical, Inc.
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K010724
Trade/Device Name: SOLA 700/500/300
Regulation Number: 878.4580
Regulatory Class: II
Product Code: FTD
Dated: March 9, 2001
Received: March 12, 2001

Dear Mr. Brennan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010724

Device Name: SOLA 700 / 500 / 300

Indications For Use:

Dräger SOLA 700 and SOLA 500 operating lights are intended for local illumination of the operating and examination area of the patient in theatres and treatment rooms.

Dräger SOLA 300 examination lights are intended for local illumination of the examination area of the patient in treatment rooms.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010724